

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 9-46 and 53-97 are pending. Non-elected claims 9-46, 53-65 and 69-92 were withdrawn from consideration by the Examiner.

Amendments to the specification and claims are fully supported by the original disclosure and, thus, no new matter is added by their entry.

The Examiner requested that the priority claim on page 1 of the specification be amended to reflect the status of parent Appln. No. 08/832,443. This was already done in the Response to Restriction Requirement filed November 2, 2004.

In response to the Examiner's requirement, the title is amended to be descriptive of the invention.

A Form PTO-1449 listing documents previously submitted or cited in a parent application was filed February 12, 2004. A copy was returned by the Examiner on July 27, 2005, but it was incomplete because the listings of non-U.S. patent documents were not initialed to acknowledge their consideration. Moreover, a copy of the Form PTO-1449 filed November 2, 2004 was not returned. A Request for Return of an Initialed Form PTO-1449 was filed August 9, 2005 but no initialed copies have been received.

The Information Disclosure Statements listing foreign patent documents and other documents comply with the requirements. It was stated on page 3 of the Action that a legible copy of each non-U.S. patent document is required. In accordance with Rule 1.98(d), however, they were submitted in compliant Information Disclosure Statements filed in an earlier application which was relied upon for an earlier effective filing date. Therefore, no further copies are required. Applicants submit that every document listed on Form PTO-1449 filed February 12, 2004 and November 2, 2004 should have been considered in the first Office Action. But to advance prosecution and ensure consideration of this information, Applicants are resubmitting herewith the Form PTO-1449 and copies of the non-U.S. patent documents not yet made of record, with the exception of Eaves et al. ("The therapeutic potential of long-term cultures of myeloid CML marrow cultures" in *The Biology of Hematopoiesis*, Daniak, ed., Alan R. Liss, NY) and Tsyrova et al. ("Improvement of leukemic LTBMCM establishment by using a specific inhibitor of

hematopoietic stem cell proliferation" in *Leukemia: Advances in Biology and Therapy – Progress and Controversies*, S326 1988) which are no longer in the possession of the undersigned. Applicants respectfully request that the PTO files be reviewed for these two documents. In a telephone conversation with the Examiner on August 2, 2005, he agreed that such resubmission would be considered. No Rule 17(p) fee is due because additional time to enable full compliance should be given. *See* 37 CFR 1.97(f).

Return of initialed copies of the Form PTO-1449 is requested. It was alleged on page 3 of the Action that search reports are not appropriate for printing on an issued patent. Applicants disagree. No such limitation on the types of document which are listed is found in the United States Code, Code of Federal Regulations, or Manual of Patent Examining Procedure. Search reports are printed documents and acknowledgment that they were considered by printing them on the patent's face is appropriate. The Examiner is respectfully requested to provide legal authority in support of his allegation.

35 U.S.C. 112 – Definiteness

Claims 93-94 and 96-97 were rejected under Section 112, second paragraph, as being allegedly "indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Applicants traverse.

Claims 93-94 and 96-97 and page 21 of the specification identify the same amino acid sequence as SEQ ID NO:1: i.e., Phe-Pro-His-Phe-Asp-Leu-Ser-His-Gly-Ser-Ala-Gln-Val. The amino acid sequence of SEQ ID NO:37 is different: i.e., (iodo)Phe-Pro-His-Phe-Asp-Leu-Ser-His-Gly-Ser-Ala-Gln-Val. It is clear that SEQ ID NOS:1 and 37 are not the same.

Applicants request withdrawal of the Section 112, second paragraph, rejection because the pending claims are clear and definite.

35 U.S.C. 112 – Enablement

Claims 66-68 and 95 were rejected under Section 112, first paragraph, because it was alleged that the specification does not reasonably provide enablement. Applicants

traverse because the specification provides an enabling disclosure for making and using the specific INPROL compounds recited in the claims.

The Examiner stated on page 3 of the Action that the specification was enabling for "a method of stimulating stem cell division in a mammal exposed to an agent which damages or destroys stem cells, comprising administering a stem cell proliferation stimulating amount of INPROL." To advance prosecution, claim 66 is amended to recite the specific INPROL compounds previously listed in claim 93. Claims 93 and 96 are amended to further limit the claimed subject matter.

Withdrawal of the enablement rejection made under Section 112, first paragraph, is requested because it would not require undue experimentation for a person of skill in the art to make and use the claimed invention.

35 U.S.C. 112 – Written Description

Claims 66-68 and 95 were rejected under Section 112, first paragraph, because it was alleged that they contain "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Applicants traverse because the specification provides an adequate written description of the specific INPROL compounds recited in the claims.

The Examiner stated on page 3 of the Action that Applicants were in possession of "a method of stimulating stem cell division in a mammal exposed to an agent which damages or destroys stem cells, comprising administering a stem cell proliferation stimulating amount of INPROL." To advance prosecution, claim 66 is amended to recite the specific INPROL compounds previously listed in claim 93. Claims 93 and 96 are amended to further limit the claimed subject matter.

Withdrawal of the written description rejection made under Section 112, first paragraph, is requested because the specification conveys to a person skilled in the art that Applicants were in possession of the claimed invention.

Double Patenting

Claims 66-68 and 93-97 were rejected under the judicially-created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-15 of U.S. Patent 6,784,155 in view of U.S. Patent 6,280,739. Applicants traverse.

There was a requirement in the parent Appln. No. 08/832,443, which issued as U.S. Patent 6,784,155, to restrict the original claims: Group XVIII (claims 47-52 in part) and Groups XXV to XXVII (claims 66-68). See Paper No. 9 mailed September 4, 1998. In the parent application, Applicants elected the subject matter of Group XVIII for prosecution and the requirement was then made final. See Paper No. 14 mailed November 24, 1999. Here, subject matter equivalent to Groups XXV to XXVII (claims 66-68) was elected for prosecution. Therefore, under 35 U.S.C. 121, a double patenting rejection cannot be made.

Withdrawal of the double patenting rejection is requested.


Conclusion

Having fully responded to all of the pending objections and rejections contained in this Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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